

# Notice of Allowability

Application No.

09/843,922

Examiner

Robert M. Kelly

Applicant(s)

FUKUMURA ET AL.

Art Unit

1633

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 10/23/06.
2. ☒ The allowed claim(s) is/are 16-18 and 22.
3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☒ All   b) ☐ Some\*   c) ☐ None   of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☒ Certified copies of the priority documents have been received in Application No. 09/720,979.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
  5. ☐ CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
    - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
      - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
    - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

## Attachment(s)

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO/SB/08),  
Paper No./Mail Date \_\_\_\_\_
4. ☐ Examiner's Comment Regarding Requirement for Deposit  
of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☐ Interview Summary (PTO-413),  
Paper No./Mail Date \_\_\_\_\_
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other \_\_\_\_\_

***Interview Summary***

On 12/15/06, Mr. Esmond, attorney for Applicant, contacted the Examiner and explained that the prior art rejections under 35 USC 103(a), relied upon a 102(e) date which does not exist. To wit, Mr. Esmond explained that the patent upon which the rejection was based relies upon a foreign priority document (Japanese Application date), for its 102(e) date, however, Mr. Esmond also explained, the Patent used does not have a PCT filing date, and simply claims priority to the Japanese document, and hence, is not eligible for a 102(e) date to the subject matter presently claimed.

The Examiner agreed to such and therefore, the attached allowance has been issued.

**EXAMINER'S AMENDMENT**

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

The application has been amended as follows:

**IN THE TITLE:**

1. The title has been amended as follows:

~~Negative Sense RNA Virus Vector of Nerve Cell~~Sendai Viral Vectors Comprising Foreign Genes Inserted Between the R1 and R2 Loci.

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The following is an examiner's statement of reasons for allowance:

Applicant's telephone argument of 12/15/06 demonstrated that the Kai Patent (6,514,728) does not make obvious the invention, because the Kai patent does not claim the subject matter required to make the instant invention obvious, and further the Kai patent is not a 371, and the foreign document (JP 10-317321) was not published until 7/25/00, which is after Applicant's priority date. Hence, Kai cannot be used as a reference in a 35 USC 103(a) rejection under the basis argued by the Examiner, and is therefore withdrawn. Further, the prior art in general only teaches the use of sendai virus as fusogenic liposome for delivery of genes, e.g., US PAT NO 5,631,237 to Dzau, et al., which liposomes do not place the foreign gene into the genome of the sendai virus, but simply use the fusogenic viral proteins/lipids for modifying the liposome to increase its efficacy in fusion. Lastly, Applicant's own non-patent filing, Sakai, et al. (1999) FEBS Lett., (1999) 456: 221-26 is the first to demonstrate that a Sendai virus could incorporate a foreign transcript stably, however, such reference was published 2 days prior to Applicant's first US filing, and hence, cannot be used as art.

In addition, in the Art, there is no other prior art reference that teaches or suggests the use of the Sendai vector by inserting a foreign gene, much less between the claimed loci, and the prior art suggests that stable integration was not reasonably expected, as demonstrated in the enablement rejections of record. In addition, the Art in general, prior to the date of invention, as demonstrated by the enablement rejections of record, did not reasonably predict that such vectors would be useful.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue

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fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."


Claims 16-18 and 22 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert M. Kelly, Art Unit 1633, whose telephone number is (571) 272-0729. The examiner can normally be reached on M-F, 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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